

Original Investigation

Characteristics and abstinence outcomes among tobacco quitline enrollees using varenicline or nicotine replacement therapy

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Received December 22, 2009; accepted February 20, 2010

Abstract

Introduction: Telephone counseling through quitlines combined with cessation medication is an effective strategy to support tobacco cessation. This study assessed the characteristics of quitline enrollees selecting varenicline (Chantix) compared with nicotine replacement therapy (NRT) medication and evaluated the cessation outcomes (7-day point prevalence) among these enrollees at 3 and 6 months after program completion.

Methods: A retrospective study analyzed demographic, tobacco use history, and abstinence outcome information of participants who enrolled in the Montana Tobacco Quit Line program and selected varenicline ($n = 3,116$) or NRT ($n = 3,697$).

Results: Participants selecting varenicline had significantly different demographic characteristics and tobacco use histories compared with enrollees selecting NRT. In the bivariate analyses, the odds of abstinence were greater among persons using varenicline compared with NRT at 3 months (22% and 13%; odds ratio [OR] = 1.85 95% CI 1.50–2.29) and 6 months (17% and 11%; OR = 1.66 95% CI 1.23–2.24). Independently, varenicline use, increasing age, having health insurance, and a greater number of counseling sessions were associated with tobacco use abstinence at 3 months. Only increasing age and a greater number of counseling sessions were independently associated with 6-month abstinence.

Discussion: Organizations providing varenicline as part of their quitline services should anticipate that participants selecting this medication have different demographic characteristics and tobacco use histories. The findings suggest that the addition of varenicline enhances 3-month abstinence rates and that the tobacco user's commitment to quit may be the most important predictor of successfully quitting.

Introduction

Tobacco use continues to be the leading cause of premature death in the United States, and millions of Americans struggle to end their addiction to tobacco. Many persons using tobacco want to quit; however, unaided cessation attempts have a low success rate (approximately 3%–5% per year; Hughes, Keely, & Naud, 2004). Cessation counseling and the utilization of medication result in higher tobacco use abstinence rates (Fiore et al., 2008). Meta-analyses of randomized clinical trials have shown that both nicotine replacement therapy (NRT) and bupropion increase the long-term tobacco abstinence rates two-fold compared with placebo (Nides et al., 2006). Recent clinical trials using varenicline, an alpha-4 β 2 nicotinic acetylcholine receptor partial agonist, found this to be an effective medication for tobacco cessation, and this drug was approved for use in the United States in 2006 (Aubin et al., 2008; Gonzales et al., 2006; Nides et al.; Tonstad et al., 2006). Randomized trials found that varenicline users were more likely to have quit at 12 months compared with placebo or NRT (34% and 40%, respectively; Aubin et al.; Tonstad et al.). Additionally, meta-analyses of multiple studies found the abstinence rate of varenicline users to be 60% greater than that of NRT users (Fiore et al., 2008).

Tobacco quitlines are a cost-effective population-based strategy to support tobacco cessation (Hopkins et al., 2001; Stead, Perera, & Lancaster, 2006; Zhu et al., 2002). Currently, the majority of quitlines in North America (98%) provide proactive multisession telephonic counseling for tobacco cessation and over half (56%) provide free or reduced-cost over-the-counter cessation medications, such as nicotine patches (Cummins, Bailey, Campbell, Koon-Kirby, & Zhu, 2007). Recent studies of quitline participants receiving NRT in addition to counseling have reported abstinence rates

doi: 10.1093/ntr/ntq045

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nearly two times higher than participants who enroll in counseling alone (An et al., 2006; Maher et al., 2007; Tinkelman, Wilson, Willett, & Sweeney, 2007). Few quitlines in North America provide free or reduced-cost prescription medications, such as varenicline or bupropion (12%), and the effects of prescription medications in addition to telephonic counseling have not been clearly documented (North American Quitline Consortium, 2009).

Beginning in May 2004, the Montana Department of Public Health and Human Services (DPHHS) implemented the Montana Tobacco Quit Line, which provides free proactive telephonic cessation counseling and NRT to Montanans enrolling in the program. In March of 2008, the quitline also began offering varenicline at a reduced cost to persons enrolling in the program because of varenicline's high quit rates in clinical trials. This paper examines the characteristics of quitline enrollees utilizing varenicline compared with NRT and the cessation outcomes among these participants 1 year after the addition of varenicline as part of the medication options available through the Montana Tobacco Quit Line.

Methods

Montana Tobacco Quit Line

Since May 2004, the Montana DPHHS has offered free proactive telephone counseling and NRT (patches, gum, or lozenges) to tobacco users enrolling in the Montana Tobacco Quit Line. The services provided by this program have been described previously (Harwell et al., 2007). Briefly, callers to the quitline can receive a number of services. Two options include: a onetime cessation information session from a trained counselor including self-help cessation education materials if desired (self-guided program) or enrollment into the proactive counseling program including up to five counseling sessions and pharmacologist assistance. Upon calling the quitline, staff conduct a brief intake assessment and collect demographic information, history of tobacco use, readiness to quit using tobacco, reasons for wanting to quit, history of previous cessation attempts, history of cessation medications used, and their history of selected chronic diseases for the programs defined above. Additionally, current tobacco use is assessed at each contact with the participant. The Montana DPHHS has marketed the program through mass media (e.g., television, radio, and newsprint advertisements) and through outreach to health care professionals and health care facilities statewide. The quitline services can be accessed directly through a toll-free telephone number or through a fax referral from a health care professional.

During the program intake call, the quitline counselors assess the participants' previous attempts to quit using tobacco and the specific cessation medications used by participants during those attempts. The counselors also discuss the medication options available through the quitline with participants who enroll into the program. Nonpregnant persons aged 18 years and older who enroll in the quitline program are eligible to receive 4 weeks of free NRT, which includes patches, gum, or lozenges, or 12 weeks of reduced-cost varenicline (Chantix). A physician's prescription is required for participants selecting varenicline, regardless of insurance status, while no prescription is required for NRT. Varenicline was added as a medication option on

17 March 2008. Participants selecting NRT are mailed 4 weeks of medication. Participants selecting varenicline are required to send a \$25.00 co-payment and mail the signed prescription for the medication or have their physician fax the prescription to a central pharmacy, which then mails 4 weeks of medication to the participant. Varenicline participants must complete the second and third counseling sessions and pay a second \$25.00 co-payment to receive the second 4-week shipment of medication. Participants must complete the fourth and fifth counseling sessions and pay a final \$25.00 co-payment to receive the last 4-week shipment. Overall, participants using varenicline pay \$75.00, and the remainder of the medication cost is provided by Montana DPHHS (during this time period, \$270.75 for 12 weeks of medication). Quitline counselors review the potential side effects of NRT and varenicline prior to initiating use of the medication and indicate that participants should contact their prescribing physician if they experience any side effects due to the medication. The central pharmacy distributing varenicline to participants also provides a summary of the potential side effects of this medication and has a toll-free telephone number available for questions.

Follow-up

The tobacco use status of a randomly selected sample of quitline callers, which included those participating in the self-guided program and those enrolling in the counseling sessions, was assessed by an independent survey agency (Pegus Research Inc.) at three 6 and 12 months after the program intake call (only 3- and 6-month data were available and reported here). Inclusion criteria for follow-up were that participants must have completed an intake call, provided the quitline with contact information, and identified themselves as a tobacco user who is personally interested in quitting. Seven telephone attempts were made to contact these eligible participants. Follow-up response rates were greater among varenicline users compared with NRT users at 3- and 6-month follow-ups (47% vs. 37% and 41% and 34%, respectively; Table 2). Upon contact with the participant, tobacco use status was assessed by asking, "Have you smoked any cigarettes or used other tobacco products in the past 7 days?" For purposes of this evaluation, the analysis includes only participants who enrolled into the program and ordered medication through the quitline.

Analysis

Data from the Montana Tobacco Quit Line operated by National Jewish Health were analyzed using SAS v.9.1 (Cary, NC). The sample included callers who enrolled in the quitline between 17 March 2008 through 16 March 2009 and who were tobacco users, aged 18 years or older, and not pregnant (Figure 1). Eleven percent (805 callers) who met the inclusion criteria but for whom medication data were missing were excluded from the analysis (Figure 1). The medication status of these participants was unknown because they were either using cessation medication, which was prescribed outside of the quitline, they were waiting for a varenicline prescription from their physician, they were not using any medication during this quit attempt, or the question was unanswered or not asked. Unadjusted and adjusted odds ratios were calculated using logistic regression to examine the likelihood that enrollees would select varenicline compared with NRT by age group, sex, education, race, health insurance status, type of tobacco user, years of tobacco use,

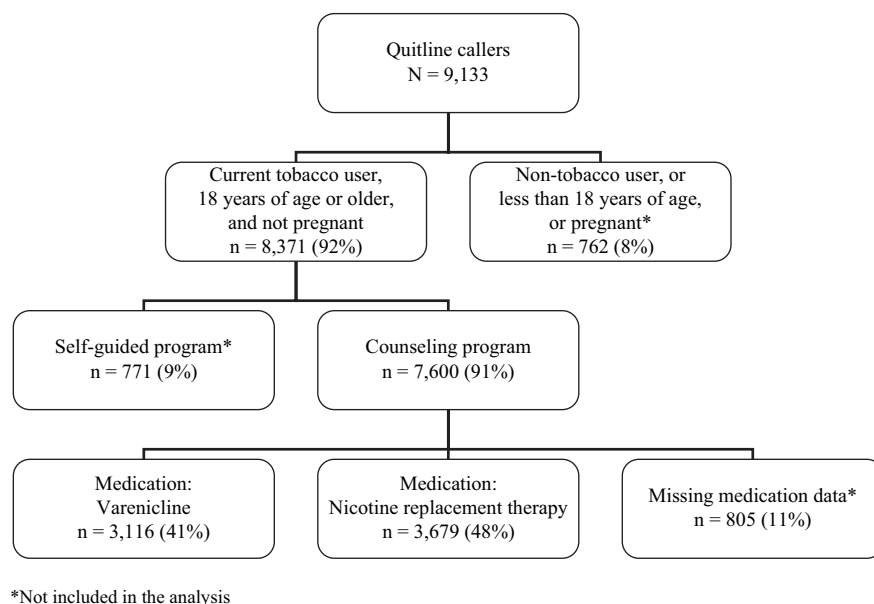


Figure 1. Number of persons contacting the Montana Tobacco Quit Line and their self-selected program enrollment and cessation medication use status, 17 March 2008 to 16 March 2009.

number of lifetime quit attempts, and number of counseling calls.

Respondents to the follow-up call who indicated that they had abstained from tobacco use in the past 7 days were considered to have quit using tobacco. Respondents who indicated that they had used tobacco in the past 7 days and nonrespondents to the follow-up survey were considered current tobacco users (intent-to-treat analysis). The unadjusted odds of 7-day abstinence using varenicline compared with NRT were calculated at 3 and 6 months after the program intake call.

To evaluate 7-day tobacco use abstinence rates among all enrollees, the adjusted odds of abstinence at 3 and 6 months after program intake call were calculated using logistic regression. The odds of 7-day abstinence at 3 and 6 months after the program intake call were adjusted for nearly all the independent variables included in the bivariate analysis. Some independent variables were excluded from the model because they had a small sample size (race) or because the variable had little variation (years of tobacco use and type of tobacco users). Education and lifetime quit attempts were excluded from the model because they were significantly ($p \leq .05$) correlated in a Pearson's chi-squared test with another independent variable in the model (insurance and greater than two counseling calls, respectively).

Results

Between 17 March 2008 and 16 March 2009, 9,133 Montanans contacted the Montana Tobacco Quit Line. Ninety-two percent of these persons were current tobacco users, who were not currently pregnant, and were 18 years and older (Figure 1). Ninety-

one percent of those persons enrolled in the quitline counseling program. Approximately half (48%) of the persons enrolling in the counseling program selected to use NRT and 41% chose varenicline.

Persons enrolling in the quitline counseling program who chose varenicline compared with NRT were more likely to be older women, have 12 or more years of education, have health insurance, smoke cigarettes, have more than 6-year duration of tobacco use, and have two or more lifetime cessation attempts compared with those without these characteristics (Table 1).

Bivariate analyses found that persons selecting varenicline (41% [1,270/3,116]) compared with NRT (22% [808/3,679]) were more likely to be not using tobacco at the last contact with the quitline (odds ratio 2.46, 95% CI 2.22–2.74). Similarly, persons choosing varenicline compared with NRT had significantly higher 7-day tobacco use abstinence rates at 3 and 6 months (Table 2).

In the multivariate analyses, the 7-day tobacco use abstinence at 3 months were significantly ($p \leq .05$) higher among persons using varenicline, older persons, persons with health insurance, and persons completing more counseling sessions compared with those without these characteristics (Table 3). After adjusting for a number of other cessation predictors, varenicline users were 28% more successful at being tobacco free (for at least 7 days) than NRT users 3 months after the program intake call (Table 3). However, at 6 months after the intake call, medication was no longer independently associated with abstinence. Quitline enrollees who completed more counseling calls (three or more calls) were nearly two and a half times more likely to be tobacco free (for at least 7 days) than those who completed less than three counseling calls (Table 3).

Table 1. Proportion of adults enrolled in the quitline utilizing varenicline compared with NRT, Montana, 17 March 2008 to 16 March 2009

	Varenicline (<i>n</i> = 3,116)	NRT (<i>n</i> = 3,679)	Odds of using varenicline compared with NRT	
	% (<i>n</i>)	% (<i>n</i>)	OR (95% CI)	AOR ^a (95% CI)
Age (years)				
18–34	32 (709)	68 (1,521)	Referent	Referent
35–54	49 (1,519)	51 (1,603)	1.87 (1.74–2.00)	1.51 (1.93–1.63)
55+	62 (888)	39 (555)	3.49 (3.04–4.00)	2.27 (1.94–2.65)
Sex				
Men	42 (1,196)	58 (1,653)	Referent	Referent
Women	49 (1,920)	51 (2,026)	1.31 (1.19–1.44)	1.19 (1.07–1.33)
Education level (years)				
<12	35 (261)	66 (495)	Referent	Referent
≥12	47 (2,780)	53 (3,137)	1.68 (1.43–1.97)	1.54 (1.30–1.83)
Unknown	62 (75)	39 (47)	2.82 (2.06–3.88)	2.37 (1.68–3.33)
Race/ethnicity				
American Indian	30 (69)	70 (159)	Referent	Referent
White	47 (2,886)	54 (3,321)	1.15 (0.95–1.39)	1.23 (1.00–1.51)
Other/unknown	45 (161)	55 (199)	1.32 (0.91–1.93)	1.51 (1.00–2.27)
Health insurance				
Yes	53 (2,146)	47 (1,898)	2.20 (1.98–2.43)	1.85 (1.66–2.06)
No	34 (881)	66 (1,711)	Referent	Referent
Type of tobacco				
Cigarettes	47 (2,925)	53 (3,306)	1.72 (1.44–2.07)	1.64 (1.34–2.02)
Other tobacco products	34 (191)	66 (373)	Referent	Referent
Years of tobacco use				
≤5	24 (67)	76 (214)	Referent	Referent
6–10	27 (98)	73 (270)	1.92 (1.70–2.16)	1.39 (1.22–1.59)
>10	48 (2,865)	52 (3,150)	3.68 (2.91–4.65)	1.94 (1.48–2.53)
Unknown	66 (86)	34 (45)	7.05 (4.96–10.04)	2.70 (1.81–4.03)
Number of lifetime quit attempts				
0–1	41 (527)	59 (749)	Referent	Referent
2–5	45 (1,487)	55 (1,832)	1.21 (1.13–1.29)	1.09 (1.02–1.18)
≥6	49 (1,020)	51 (1,047)	1.46 (1.28–1.66)	1.20 (1.03–1.39)
Unknown	62 (82)	38 (51)	1.76 (1.45–2.13)	1.31 (1.05–1.63)
Number of counseling calls				
0–2 counseling calls	37 (1,825)	63 (3,056)	Referent	Referent
3–5 counseling calls	67 (1,291)	33 (623)	3.47 (3.10–3.88)	3.07 (2.73–3.46)

Note. AOR = adjusted odds ratio; NRT = nicotine replacement therapy; OR = odds ratio.

^aAdjusted for all other independent variables in the table.

Discussion

Our findings suggest that Montana Tobacco Quit Line enrollees selecting varenicline compared with NRT have significantly different demographic characteristics and tobacco use histories. Participants selecting varenicline had significantly higher abstinence rates at 3 and 6 months compared with those selecting NRT. However, medication type was no longer a significant independent predictor of abstinence at 6 months after adjusting for other factors. In the multivariate analyses, increasing age and completion of more counseling sessions were independently associated with tobacco use abstinence at 6 months.

Evaluating the effect of medication alone, we found that persons using varenicline were more likely to be tobacco free

compared with those using NRT at both 3 and 6 months. These findings are similar to randomized trials and meta-analyses comparing varenicline with NRT (Aubin et al., 2008; Fiore et al., 2008). Previous studies have found that the addition of cessation medication (such as NRT) to state quitline programs increases the abstinence rate among participants (An et al., 2006; Fellows, Bush, McAfee, & Dickerson, 2007; Maher et al., 2007; Tinkelman et al., 2007). This study adds evidence to the existing literature that offering discounted non-nicotine medication coupled with telephone cessation counseling through a state quitline program is effective. The quit rates reported here and in other studies of quitline programs, which have paired behavioral and pharmacological cessation treatments, are all higher than the estimated 3%–5% quit rate of unassisted quit attempts (Hughes et al., 2004).

Table 2. Abstinence^a rate at 3 and 6 months after the program intake call reported by adults enrolled in the quitline by medication choice, Montana, 17 March 2008 to 16 March 2009

Follow-up period by medication	Attempted calls, <i>n</i>	Response rate % (<i>n</i>)	Responder quit rate ^b % (<i>n</i>)	Intention-to-treat quit rate ^c % (<i>n</i>)	Odds of abstinence (OR 95% CI) ^c
3 months					
NRT	1,294	36 (460)	37 (170)	13 (170)	Referent
Varenicline	1,202	47 (561)	47 (263)	22 (263)	1.85 (1.50–2.29)
6 months					
NRT	717	33 (236)	33 (79)	11 (79)	Referent
Varenicline	751	41 (309)	41 (128)	17 (128)	1.66 (1.23–2.24)

Note. NRT = nicotine replacement therapy; OR = odds ratio.

^aAbstinence—Adult quitline enrollees were considered abstinent if they report having not used any tobacco product in the 7 days prior to the follow-up time period.

^bResponder quit rate—Respondents who indicated that they had abstained from tobacco use in the past 7 days were considered to have quit using tobacco, and respondents who indicated that they had used tobacco in the past 7 days were considered current tobacco users. Nonrespondents were not included.

^cIntention-to-treat rates—Respondents who indicated that they had abstained from tobacco use in the past 7 days were considered to have quit using tobacco. Respondents who indicated that they had used tobacco in the past 7 days and nonrespondents were considered current tobacco users.

Multivariate analyses revealed that only two factors, older age and a greater number of counseling sessions, were independently associated with tobacco use abstinence at 6 months. Meanwhile, medication type was independently associated with cessation at 3 months but not at 6 months. Given the time and financial commitment (required counseling sessions to receive medication and co-pay for medication) required of varenicline users by the Montana Tobacco Quit Line, we speculate that the program was biased toward a successful quit attempt among varenicline users compared with NRT in the short term, as seen at 3-month follow-up. Therefore, the independent association between medication and cessation that was observed at 3 months may reflect the varenicline user's commitment to quit as prescribed by the Montana Tobacco Quit Line. However, at 6 months, regardless of the medication the tobacco user selected, their participation in more counseling sessions was independently associated with cessation. The independent association between greater number of counseling sessions and cessation found in this study is consistent with the conclusions of the 2008 U.S. Public Health Service Clinical Practice Guideline: the effectiveness of telephone counseling increases with treatment intensity (i.e., more counseling sessions; Fiore et al., 2008).

There are a number of limitations to consider when interpreting the results of this study. First, we did not have a control group by which to compare the use of varenicline or NRT in addition to telephonic counseling. Not all quitline enrollees who participated in counseling used medication through the quitline in their quit attempt (*n* = 805), and the medication use status for this subgroup was not ascertained. Additionally, the sample of these participants completing the 3- and 6-month follow-up calls to assess abstinence outcomes was too small to calculate stable estimates. Second, treatment courses offered through the Montana Tobacco Quit Line were not equal between varenicline (12 weeks) and NRT (4 weeks), which may explain the difference found at 3-month follow-up between the two medication groups. Further research is needed to compare the efficacy of varenicline and NRT in a real world setting in

which the treatment courses are equal. Third, cessation was assessed through individual self-report rather than through biochemical measures. However, meta-analysis has found that self-reported cessation is accurate (Patrick et al., 1994). Fourth, this study analyzed abstinence outcome data using the intention-to-treat method, which underestimates any difference found between the two medication groups, provided that the response rate was approximately equal between the two groups. However, response rates were lower among NRT users than among varenicline users at 3- and 6-month follow-up periods. This could have resulted in an overestimate in the difference between abstinence rates of varenicline users compared with NRT users, had a difference been found. Fifth, the U.S. Food and Drug Administration recently warned against possible behavioral side effects of varenicline (United States Department of Health and Human Services & Food and Drug Administration, 2009). This study did not evaluate side effects that quitline enrollees using varenicline or NRT may have experienced, although the quitline recommended that users consult with a primary care provider about any side effects they may experience. Finally, this study was only able to evaluate short-term abstinence outcomes (3 and 6 months after program completion). Future research is needed to assess the long-term abstinence outcomes of varenicline in addition to telephone cessation counseling. Additionally, further research is needed to compare tobacco use abstinence rate among quitline enrollees using NRT or varenicline in a setting where the requirements are the same regardless of medication type.

To our knowledge, this is the first study to compare the characteristics and abstinence outcomes of quitline enrollees using varenicline or NRT in a nonclinical trial setting. We found that varenicline users were, in general, long-time tobacco users who had numerous unsuccessful quit attempts over their lifetime. Although medication type was no longer an independent predictor of cessation at 6 months, offering varenicline as a benefit option of the Montana Tobacco Quit Line offered these tobacco users a promising new aid to help them quit. Our findings indicate that

Table 3. Odds of abstinence^a at 3 and 6 months after the program intake call among adults enrolled in the quitline receiving varenicline or NRT, Montana, 17 March 2008 to 16 March 2009

Predictors of abstinence	3 months ^b (n = 2,424)		6 months ^b (n = 1,422)	
	AOR ^c (95% CI)	p value	AOR ^c (95% CI)	p value
Pharmacotherapy				
NRT	Referent		Referent	
Varenicline	1.28 (1.02–1.62)	.04	1.12 (0.81–1.56)	.49
Sex				
Men	1.05 (0.83–1.32)	.68	1.14 (0.83–1.58)	.42
Women	Referent		Referent	
Age (years)				
18–34	Referent		Referent	
35–54	1.33 (1.14–1.55)	<.01	1.46 (1.17–1.82)	<.01
≥55	1.77 (1.30–2.42)	<.01	2.13 (1.37–3.32)	<.01
Health insurance				
No	Referent		Referent	
Yes	1.50 (1.17–1.92)	<.01	1.25 (0.88–1.77)	.21
Tobacco use ^d				
Not a heavy user	1.14 (0.87–1.47)	.34	1.18 (0.83–1.69)	.36
Heavy user	Referent		Referent	
Number of counseling calls				
0–2 counseling calls	Referent		Referent	
3–5 counseling calls	2.42 (1.93–3.03)	<.01	2.44 (1.77–3.35)	<.01

Note. AOR = adjusted odds ratio; NRT = nicotine replacement therapy.

^aAbstinence—Adult quitline enrollees were considered abstinent if they report having not used any tobacco product in the 7 days prior to the follow-up time period.

^bIntention-to-treat rates—Respondents who indicated that they had abstained from tobacco use in the past 7 days were considered to have quit using tobacco. Respondents who indicated that they had used tobacco in the past 7 days and nonrespondents were considered current tobacco users.

^cAdjusted for all other independent variables in the table.

^dHeavy tobacco user is defined as smoking one or more packs of cigarettes per day or five or more cans of spit tobacco per week.

the tobacco user's commitment to quit may be the most important predictor of successfully quitting.

Funding

This work was supported through a cooperative agreement with the Centers for Disease Control and Prevention, Office on Smoking and Health (1U58DP001977-01) in Atlanta, GA, and the Montana State Legislature (House Bill 2).

Declaration of Interests

None declared.

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